Atty. Dkt. No. 047940-0167

NETHE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Uri GALILI et al.

Title: IMMUNE TOLERANCE TO

PREDETERMINED ANTIGENS

Appl. No.: 10/789,955

Filing Date: 02/27/2004

Art Unit: 1644

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date below.

Kathryn E. Cox

(Printed Name)

Codd

(Signature)

March 17, 2005

(Date of Deposit)

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.56

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO-1449 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document, except as noted below, is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The USPTO has waived the requirement under 37 CFR 1.98(a)(2)(i) to submit copies of U.S. patents and U.S. patent application publications when citing and submitting an Information Disclosure Statements in a patent application filed after June 30, 2003 and in an international application that has entered the national stage under 37 USC §371 after June 30, 2003. Accordingly, copies of these types of documents are not being supplied in connection with this application. Reference is being made to OG Notice dated August 5, 2003, Information Disclosure Statements May Be Filed Without Copies of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO-1449 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-2350. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-2350.

Respectfully submitted,

Date March 17, 2005

FOLEY & LARDNER LLP Customer Number: 23524

Telephone:

(608) 258-4277

Facsimile:

(608) 258-4258

Kathryn E. Cox

Attorney for Applicants

By Kathryn E. Cox

Registration No. 55,089

	1	(A)							
Form PTO-1449		D'S DEPARTMENT OF COMMERCE			ATTY. DOCKET NO.		SERIAL NO.		
(MODIFIED)		PATENT AND TRADEMARK OFFICE		047940-0167		10/789,955			
					APPLICANT				
INFO	ORMAT	ON DISCLOSURE	CITATION		U:	ri GALILI	et al.		
Submitted: March 17, 2005					FILING DATE		GROUP ART UNIT		
(Use several sheets if necessary)				02/27/2004		1644			
			U.S. PA	TEN	T DOCUMENTS		<u></u>		
	<u> </u>	DOGUMENT					<u></u>	FILING	DATE
EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE		NAME	CLASS	SUB- CLASS	FILING DATE IF	
		NOWBER						APPROPRIATE	
		5,879,675	3/9/99	Galili et al.					
		2004/0009906	1/15/04	Kakkis, <i>et al</i> .					
		60/548,700	2/27/04	Gali	li et al.				
		•	FOREIGN	PAT	ENT DOCUMENTS				
	DEE	DOCUMENT	DATE		COUNTRY	CLASS	SUB-	TRANSLATION	
	REF	NUMBER	DATE		COUNTRY	CLASS	CLASS	YES	NO
		WO 95/24924	9/21/95	PC1	-				
	İ								
		OTHER DOCU	MENTS (Includi	ing A	uthor, Title, Date, Perti	nent Pages,	Etc.)		
		Fink, et al., "Cloned Immunol, 133 (4), p			suppress primary cytotoxiostract).	c responses o	lirected agair	st them."	J .
		Streilein, et al., "Are allogeneic and associative recognition coincident T cell paradigms?" <i>Transplantation</i> , 31 (3), pp. 183-6, 1981 (abstract).							
		Prange, et al., "Induction of partial immune tolerance in a closely-related species system by a single injection of papain-extracted, donor species specific, lymphocyte membrane antigens." Z Exp Chir 13 (1), pp. 28-37, 1980 (abstract).							
		Ildstad, et al., "Effect of selective T cell depletions in mixed xenogeneic reconstitution on specific hyporeactivity to transplantation across a species barrier," <i>Transplantation</i> , 41 (3) pp. 372-6, 1986 (abstract).							
		Zepp, et al., "Intrathymic tolerance induction: determination of tolerance to class II major histocompatibility complex antigens in maturing T lymphocytes by a bone marrow-derived non-lymphoid thymus cell," Scand J Immunol, 26 (6) pp. 589-601, 1987 (abstract).							
		Aldo-Benson. "Membrane depolarization is induced in tolerant B lymphocytes by stimulation with antigen," <i>Cell Immunol</i> , 103 (2) pp. 417-25, 1986 (abstract).							
		Ambrosius, "Modification of the immune reaction by antigen-immunosuppressive-agent conjugates. I. Tentative hypothesis for the induction of antigen-specific suppression by antigen-immunosuppressive-agent conjugates," <i>Acta Biol Med Ger</i> 35 (12), pp. 1677-85, 1976 (abstract).							
		Schrader, "Tolerance induction in B lymphocytes but thymus-dependent antigens. T cells may abrogate B-cell tolerance induction by prevent an antibody response," <i>J Exp Med</i> , 141 (5) pp. 974-89, 1975 (abstract).							
	Schrader, "The in vitro induction of immunological tolerance in the B lymphocyte by oligovalent thymus-dependent antigens," <i>J Exp Med</i> , 141 (5) pp. 962-73, 1975 (abstract).						-		

	Mullen, et al., "Characteristics of specific unresponsiveness toward kidney and skin allografts in adult rats inoculated at birth with allogenic bone marrow or kidney cells across a strong H-1 barrier," <i>Transplantation</i> , 20 (4) pp. 281-90, 1975 (abstract).
	Klaus, "B cell tolderance induced by polymeric antigens VI. Kinetics and reversibility of the inhibition of antibody-forming cells by antigen," <i>Eur J Immunol</i> , 6 (6) pp. 389-93, 1976 (abstract).
	Ratner, et al., "Immunology of renal allograft rejection," Arch Pathol Lab Med, 115 (3) pp. 283-7, 1991 (abstract).
	Webb, et al., "Induction of neonatal tolerance to MIsa antigens by CD8 + T cells," Science, 248 (4963) pp. 1643-6, 1990 (abstract).
	Kao, "Induction of humoral immune tolerance to major histocompatibility complex antigens by transfusions of UVB-irradiated leukocytes," <i>Blood</i> , 88 (11) pp. 4375-82, 1996 (abstract).
	Suzuki, et al., "Regulation by differential development of Th1 and Th2 cells in peripheral tolerance to cardiac allograft induced by blocking ICAM-1-LFA-1 adhesion," Circulation, 96 (7) pp. 2247-2253, 1997 (abstract).
	McCarthy, et al., "A comparison of the neonatal tolerance-inducing capacities of H-2 class II antigens," <i>J Immunol</i> , 131 (4) pp. 1670-5, 1983 (abstract).
	Hasek, et al., "Comparison of neonatally and adoptively induced transplantation tolerance in mice," Folia Biol (Praha), 26 (3) pp. 167-75, 1980 (abstract).
	Pike, et al., "Clonal anergy: the universally anergic B lymphocyte," <i>Proc Natl Acad Sci USA</i> , 79 (6) pp. 2013-7, 1982 (abstract).
	Gnezditskaia, et al., "Immunofluorescence study of lactoferrin-synthesizing thymus cells," <i>Biull Eksp Biol Med</i> , 90 (11) pp. 580-3, 1980 (abstract).
	Collavo, et al., "T lymphocyte tolerance and early appearance of virus-induced cell surface antigens in Moloney-murine leukemia virus neonatally injected mice," <i>J Immunol</i> , 126 (1) pp. 187-93, 1981 (abstract).
	Fujiwara, et al., "Tolerance inducibility and the elicitation of autoantibodies by LPS in aged NZB mice," <i>J Clin Lab Immunol</i> , 3 (3) pp. 185-8, 1980 (abstract).
	Sadigursky, et al. "Induced tolerance to schistosoma mansoni antigens modulates periovular granuloma," Mem Inst Oswaldo Cruz, 82 (4) pp. 279-271, 1987 (abstract).
	Takizawa, et al., "Spontaneous regression in murine hypersensitivity pneumonitis: lack of immunological tolerance," <i>Int Arch Allergy Appl Immunol</i> , 89 (2-3), pp. 173-180,1989 (abstract).
	Henion, T.R., et al., "Synthesis of α -gal epitopes on influenza virus vaccines, by recombinant α 1,3galactosyltransferase, enables the formation of immune complexes with the natural anti-Gal antibody," <i>Vaccine</i> 15 (11), pp. 1174-1182, 1997.
	Bracy, J.L., et al., "Induction of B-cell tolerance by retroviral gene therapy," Blood 96 (9), pp. 3008-3015, 2000.
	Bell, et al., "Persisting T cells in rats tolerant of human serum albumin. The significance of tolerant and nonimmune T cells which preferentially restrict high affinity antibody synthesis," Eur J Immunol 5 (7) pp. 481-486, 1976 (abstract).
	Zan-Bar, et al. "Studies on suppressor T Cells in tolerance," Adv Exp Med Biol, 66 pp. 585-592, 1976 (abstract).
	Silverman, "Engineered B Cell superantigens and immune tolerance," National Institute of Allergy and Infectious Diseases, 2001 (abstract).
	Bromberg, "Transplantation tolerance: T cell trafficking," National Institute of Allergy and Infectious Diseases, 2001 (abstract).
	Blakely, et al. "Indefinite survival following small intestinal transplantation after intrathymic injection of the donor with recipient-type splenocytes in a rat model," <i>Transplantation</i> 59 (2) pp. 309-311, 1995 (abstract).
	Acres, Robert B. "Neonatally induced immune tolerance to soluble protein antigens," <i>Cell Immunol</i> 43-12B , p. 3913, 1982 (abstract).
	Chatenoud, et al. "Anti-CD3 antibody induces long-term remission of overt autoimmunity in nonobese diabetic mice," <i>Proceedings of the National Academy of Sciences of the United States of America</i> 91 (1) p. 123-127, 1994 (abstract).
	Liu, et al., "T cell recognition of self-human histocompatibility leukocyte antigens (HLA)-DR peptides in context of syngeneic HLA-DR molecules," <i>J Exp Med</i> 175 (6) pp. 1663-1668, 1992 (abstract).
·	

Hoffmann, et al., "Regulation of T cell function by Mtv-7 gene products," Semin Immunol 4(5) pp. 337-351, 1992 (abstract).
Dannecker, et al., "In vivo presentation of MIs-1 antigen by T and B lymphocytes," <i>Immunobiology</i> 185 (1) pp. 20-27, 1992 (abstract).
Hosono, et al. "Neonatal tolerance induction in the thymus to MHC-class-II-associated antigens. V. Thymus medulla and the site for deletional signaling achievement in MIS tolerance," <i>Thymus</i> 20 (1) pp. 31-45, 1992 (abstract).
Miconnet, et al., "MIs-1a-induced peripheral tolerance to host minor histocompatability antigens in radiation bone marrow chimeras. Modification of T cell repertoire associated with active suppression and permanent presentation of host antigens," <i>J Immunol</i> 148 (12) pp. 3706-3713, 1992 (abstract).
Kang, et al., "Transactivation by AP-1 is a molecular target of T cell clonal anergy," <i>Science</i> 257 (5073) pp. 1134-1138, 1992 (abstract).
Ideyama, et al., "Intrathymic induction of neonatal tolerance to MIs-1a determinant: clonal deletion and clonal anergy by haematolymphoid cells," <i>Immunology</i> 74 (2) pp. 240-245, 1991 (abstract).
Dannecker, et al., "Induction of neonatal tolerance to the MIs-1a self-super-antigen. Time kinetics and MHC restriction," <i>J Immunol</i> 147 (9) pp. 2833-2838, 1991 (abstract).
Kronenberg, "Self tolerance and autoimmunity," Cell 65 (4) pp. 537-542, 1991 (abstract).
Halliday, et al., "Presentation of antigen to suppressor cells by a dimethylbenz (a) anthracene-resistant, lapositive, Thy-1-negative, I-J restricted epidermal cell," <i>Immunology</i> 69 (1) pp. 97-103, 1990 (abstract).
Nishimura, et al., "The induction of skin xenograft tolerance in rat-to-mouse combination could be affected by DFR mediating cells and antibodies against rat bone marrow cells as well as NK cells in the cyclophosphamide-induced tolerance system," <i>Immunobiology</i> 193 (5) pp. 420-438, 1995 (abstract).
Lagoo-Deenadayalan, et al., "Donor specific bone marrow cells suppress lymphocyte reactivity to donor antigens and differentially modulate TH1 and TH2 cytokine gene expression in the responder cell population," <i>Transpl Immunol</i> 3 (2) pp. 124-134, 1995 (abstract).
Todd, et al., "T cell activation is not a prerequisite for peripheral tolerance induction to M1s 1a.," <i>Cell Immunol</i> 154 (1) pp. 380-392, 1994 (abstract).
Viciana, et al., "Differential patterns of T cell clonal deletion in neonatal H-2 tolerance and I-E/MIs induced self-tolerance," <i>Transpl Immunol</i> 2 (3) pp. 208-217, 1994 (abstract).
Aitouche, et al., "Reversal of chimera donor-to-host tolerance in a tolerogen-free environment. Evidence of a nondeletional mechanism," <i>Transplantation</i> 58 (4) pp. 491-496, 1994 (abstract).
Dahmen, et al., "Split tolerance induced by orthotopic liver transplantation in mice," <i>Transplantation</i> 58 (1) pp. 1-8, 1994 (abstract).
Eynon, et al., "Parameters of tolerance induction by antigen targeted to B lymphocytes," <i>J Immunol</i> 151 (6) pp. 2958-2964, 1993 (abstract).
Huang, et al., "Superantigen-driven peripheral deletion of T cells. Apoptosis occurs in cells that have lost the alpha/beta T cell receptor," <i>J Immunol</i> 151 (4) pp. 1844-51, 1993 (abstract).
Gollob, et al., "Aberrant induction of T cell tolerance in B cell suppressed mice," <i>J Immunol</i> 150 (9) pp. 3705-3712, 1993 (abstract).
Melamed, et al., "Direct evidence for anergy in T lymphocytes tolerized by oral administration of ovalbumin," Eur J Immunol 23 (4) pp. 935-942, 1993 (abstract).
Yang, et al., "Cardiac allograft tolerance induced by intra-arterial infusion of recombinant adenoviral CTLA4Ig," <i>Transplantation</i> 67 (12) pp. 1517-1523, 1999 (abstract).
Van Parijs, et al., "Mechanisms of peripheral T cell tolerance," <i>Novartis Found Symp</i> 215 pp. 5-14, 1998 (abstract).
Leon, et al., "Natural and induced tolerance in an immune network model," <i>J Theor Biol</i> 193 (3) pp. 519-534, 1998 (abstract).
Shen, et al., "Regulation of T cell immunity and tolerance in vivo by CD4," Int Immunol 10 (3) pp. 247-257, 1998 (abstract).
Garside, et al., "Lymphocytes from orally tolerized mice display enhanced susceptibility to death by apoptosis when cultured in the absence of antigen in vitro," Am J Pathol 149 (6) pp. 1971-1979, 1996 (abstract).

EXAMINER		DATE CONSIDERED				
	Ogawa, et al., "Induction of immune tolerance to a transplantation carbohydrate antigen by gene therapy with autologous lymphocytes transduced with adenovirus containing the corresponding glycosyltransferase gene," Gene Therapy 11 pp. 292-301, 2004.					
	Shlomai, et al., "Immunomodulation of experimental colitis: the role of NK1.1 liver lymphocytes and surrogate antigens-bystander effect," <i>J Pathol</i> 195 pp. 498-507, 2001 (abstract). Maeda, et al., "Suppressor T cells regulate the nonanergic cell population that remains after peripheral tolerance is induced to the MIs-1 antigen in T cell receptor Vbeta 8.1 transgenic mice," <i>Proc Natl Acad Sci USA</i> 97 (24) pp. 13257-13262, 2000 (abstract). Birk, et al., "Alternative activation of antigen-presenting cells: concepts and clinical relevance," <i>Hautarzt</i> 52 pp. 193-200, 2001 (abstract).					
	Guermonprez, et al., "Antigen presentation 621-667, 2002 (abstract).	and T cell stimulation by dendritic cells," Annu Rev Immunol 20 pp.				
	Liang, et al., "Molecular mimicry and the ro Cellular and Molecular Life Sciences 57 (4	ole of B lymphocytes in the processing of autoantigens." CMLS pp. 561-568, 2000 (abstract).				
	Davies, et al., "T cell suppression in transp pp. 3602-3607, 1996 (abstract).	lantation tolerance through linked recognition," J Immunol 156 (10)				

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include any copy of this form with next communication to applicant.